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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/613,961	FLICK, A. BART	
	Examiner	Art Unit	
	Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on th cov r sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-19,23 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-19,23 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/9/04 has been entered. Accordingly, claims 1, 19, 23, 25, 26, 31 and 32 have been amended.

2. Claims 1, 3-19, 23 and 25-32 are pending in the instant application.

Information Disclosure Statement

3. The information disclosure statement filed 2/9/04 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Objections

4. Claim 15 is objected to because of the following informalities:

Claim 15, line 7"form" should read --form--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,520,664 ("Bricault, Jr. et al.").

As regards claims 1 and 4, Bricault, Jr. et al. disclose polymeric implants (col. 4, lines 64 and 65) having antimicrobial coatings, such as, gold, silver, platinum, *etc.*

The applicant should note that silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates.

This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. When the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material is introduced into the wound, an antimicrobial or analgesic effect occurs. This effect is well known in the art, which is why silver is widely used as an additive to wound dressings. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

Although Bricault, Jr, et al. fail to explicitly teach that the medical device is configured to lower the pathology's electrical potential when the at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology, it is deemed that the pathology's electrical potential of the would necessarily be lowered as an intrinsic consequence of the placement of the device within the user's body because Bricault, Jr. et al. is employing the same conductive material as the applicant.

Moreover, the applicant should note the device of Bricault, Jr. et al. is capable of producing a lateral shift in the electrical potential of a pathology.

Bricault, Jr. et al. fail to explicitly teach that the resistance of the metals is less than 1000 ohms/cm. However, since the applicant discloses some of the same conductive materials as those disclosed by Bricault, Jr. et al., (*e.g.*, silver and gold), it is inherent that the same metals have the same resistance. Note applicant's admitted disclosed resistances on page 32-33 of the specification.

As regards claims 13 and 14, Bricault, Jr. et al. disclose a tubular shaped catheter (Figs. 5 and 6a), which is capable of draining a wound or body cavity (thereby being a wound drain).

7. Claims 1, 4, 19, 23, 25-32 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,004,667 ("Sakurada et al.").

As regards claims 1 and 4, Sakurada et al., disclose a bandage or wound dressing comprising a fibrous substrate coated with silver or nickel, which inherently has

a resistance of 1000 ohm/cm or less, according to applicant's own admission (see the specification).

Sakurada et al. also disclose that **the metallic ions may be distributed into the body without galvanic cell action** (col. 5, line 43-48, col. 6, lines 32-39 and col. 12, line 21- col. 13, line 22), thereby being configured to passively alter the pathology. As regards lowering the electrodynamic process of a portion of the body, silver and other antimicrobial metals inherently possess the property of altering an electrodynamic process of a portion of the body in which they contact, specifically the portion of the body containing wound exudates.

This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. When the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material is introduced into the wound, an antimicrobial or analgesic effect occurs. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

As recited above, it is deemed that the pathology's electrical potential of the would necessarily be lowered as an intrinsic consequence of the placement of the device within the user's body because Bricault, Jr. et al. is employing the same conductive material as the applicant.

Moreover, the applicant should note the device of Sakurada et al. is capable of producing a lateral shift in the electrical potential of a pathology.

As regards claims 19, 23, 28 and 29, Sakurada et al. disclose a medical device (bandage) for treating a portion of the body, comprising at least one layer of a conductive material (201) coated with silver or nickel, having an inherent resistance of less than 1000 ohms/cm (see the specification). At col. 12, Sakurada et al. disclose that a dual layer of conductive material may be used.

Sakurada et al. further disclose that the conductive layer inherently comprises a biologically inert polymer since it is used on the human body, wherein no galvanic cell action or external energy source is required to alter an electrodynamic process or electric parameters of the portion of the body.

As recited above, it is deemed that the pathology's electrical potential of the would necessarily be lowered as an intrinsic consequence of the placement of the device within the user's body because Bricault, Jr. et al. is employing the same conductive material as the applicant. As such, steps (b) and (c) inherently occur when the metallic ions from the medical device enter the body.

It is deemed an intrinsic consequence that the medical device interiorly shifts a pathology's maximum electrical resistance when in contact with the pathology **(claim 23).**

As regards claims 25 and 26, silver is known to produce an analgesic effect, therefore the migration of the metallic silver ions into the body is capable of producing an analgesic effect. Additionally, silver is an antimicrobial agent, which helps to heal wounds faster.

As regards claim 27, note col. 12, lines 44-46, which discloses that a moisture vapor impermeable film may be provided over the polymer to prevent evaporation of the fluid.

As regards claim 30, the substrate is coated with conductive material, therefore the surface of the substrate has the conductivity of the conductive material, which has an inherent resistance of less than 1000 ohms/cm (see the specification).

As regards claims 31 and 32, Sakurada et al. disclose at col. 12, 58-59 may include a dual layer of conductive material. Also, it is deemed an intrinsic consequence that the device interiorly shift a pathology's maximum electrical resistance when in conductive contact with the pathology.

8. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,615,705 ("Scales et al.")

As regards claim 6, Scales et al. disclose antimicrobial implants (*e.g.*, orthopaedic plates, pins and artificial joints) comprising at least one layer of conductive material (metallic silver). Applicant admits in the specification that silver has a resistance of less than 1000 ohm/cm. Scales et al. further disclose that the layer of conductive material is coated on an implant constructed from a bioinert material (*e.g.*, a non-toxic synthetic plastics material (polymer).

The applicant should note that it is inherent in the disclosure that no external energy or galvanic cell action is required to alter an electrodynamic process of a portion of the body since the application of silver ions to the body inherently performs the

function of altering the electrodynamic process of a portion of the body to which it is applied.

This is a natural occurrence since wound fluid contains electrolytes, thereby being electrically conductive. When the metallic material is placed in contact with wound fluid, an electrochemical reaction takes place, and depending upon the amount of metallic material is introduced into the wound, an antimicrobial or analgesic effect occurs. Such effect is produced through an alteration/shift in the electrical potential of the wound fluid in and around the wound site.

As recited above, it is deemed that the pathology's electrical potential of the would necessarily be lowered as an intrinsic consequence of the placement of the device within the user's body because Bricault, Jr. et al. is employing the same conductive material as the applicant.

Moreover, the applicant should note the device of Sakudura et al. is capable of producing a lateral shift in the electrical potential of a pathology.

The examiner concedes that at col. 3, lines 68-col. 4, line 3, Scales et al. mentions that in order to promote galvanic action producing silver ions, specific silver alloys may be used. However, the applicant is directed to col. 4, lines 49-52, wherein it is disclosed that silver ions are produced using metallic silver and col. 5, lines 24-31, wherein it is disclosed that silver ions are produced using bioerosion.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scales et al.

As regards claim 7, Scales et al. fail to teach the medical appliance a dental appliance. However, the examiner contends that the technology used to the apply metal coatings to the pins and plates of the disclosed endoprosthetic implants of Scales et al., can also be used to coat dental appliances.

Furthermore, the examiner contends that dental implants are a form of an endoprosthetic implant. And, one having ordinary skill in the art would have been motivated to place an antimicrobial coating on any implant, including a dental implant (appliance) for the purpose of preventing antimicrobial growth thereon.

12. Claims 3, 5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurada et al.

As regards claim 3, Sakurada et al. fail to teach the substrate is constructed from polyester and acrylic fibers or a gauze. However, since gauze is conventionally constructed material, such as, for example, cotton, one having ordinary skill in the art would have found it obvious to select cotton gauze because it is breathable.

Additionally, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

As regards clams 5 and 8-12, Sakurada et al. fail to teach the bandage is shaped for use around external fixture pin structures, shaped for use around ostomy sites, shaped for use around tracheostomy sites, shaped for use around catheter sites, and shaped for packing body cavities. However, it has been held that the shape of a prior art device is a design consideration within the level of ordinary skill in the art. In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). As such, one having ordinary skill in the art would have found it obvious to change the shape of the bandage to fit the portion of the body for which the device is intended.

Allowable Subject Matter

13. Claims 15-18 are allowed.

Response to Arguments

14. Applicant's arguments filed 2/9/04 have been fully considered but they are not persuasive. Applicant's principal argument is that the examiner has not provided any extrinsic evidence that shows that the lowering of the pathology's electrical potential when at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology, that the conductive medical devices as presently claimed can induce analgesic effect by lowering the electrical potential of a pathology, and that the medical devices interiorly shifts a pathology's maximum electrical resistance, for example from a surface region to a subsurface region. Applicant additionally argues that the rejections are based on impermissible hindsight in view of applicant's disclosure. In response, the examiner contends that the applicant has neither disclosed in the specification nor in the claims, a feature that accomplishes the claimed functions other than the metal (silver) coated fibers. Since the examiner has provided the applicant with prior art disclosing (metal) silver coated fibers, and with the general knowledge of how silver ions migrate from silver coated medical devices to produce antimicrobial and analgesic effects, applicant's invention as presently claimed are either anticipated or made obvious by the recited prior art references (note rejections above).

The applicant should note the recited effect of lowering of the pathology's electrical potential when at least one conductive layer is positioned to conductively bridge healthy surfaces surrounding the pathology, that the conductive medical devices as presently claimed can induce analgesic effect by lowering the electrical potential of a pathology, and that the medical devices interiorly shifts a pathology's maximum

electrical resistance, for example from a surface region to a subsurface region, are an intrinsic consequence of placing the devices of Bricault, Jr. et al., Sakurada et al., and Scales et al. on a user.

The examiner invites the applicant to provide evidence of the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kim M. Lewis
Primary Examiner
Art Unit 3743

Kml
June 1, 2004